

REMARKS

Claims 1, 2, and 4-35 are pending. Claims 15 and 29 are withdrawn. Claims 1, 2, 4-14, 16-28, and 30-35 are rejected. No claims are amended.

Claim Rejections under 35 U.S.C. § 103(a):

Claims 1, 2, 4-14, 16-28, and 30-35 have been rejected as obvious over US Patent 6,130,200 to Brodbeck et. al. (“Brodbeck”) in view of US Patent 5,628,993 to Yamagata et. al. (“Yamagata”) and US Patent 6,096,339 to Ayer et. al. (“Ayer”). Applicants traverse this rejection on the basis that the Office has not established a proper prima facie case of obviousness.

To demonstrate prima facie obviousness, the Office must make a determination as to motivation to modify the primary reference(s) to arrive at the claimed invention. MPEP 2144.08. In this case, the Office has failed to provide motivation to utilize compressed particulates as recited in the claimed invention.

First, Applicants note that Brodbeck does not itself teach compression of drug particles, contrary to the Office’s assertions. OA at 7. The process that is referred to by the Office is actually “spray-drying” – which is exactly the term used in Brodbeck. One of skill in the art would recognize the resulting particles as “spray-dried particles” and not compressed particles. The Office additionally notes that Brodbeck does not teach crushing a compressed mass of active agent. OA at 4.

However, there is no express teaching pointed out by the Office as to why one of skill would have chosen compression of an active agent and hydrophobic agent particulate – other than impermissible hindsight reconstruction of the invention by the Office.

Yamagata fails to teach the criticality of compression. A broad genus of preparation methods are

disclosed in Yamagata – but compression is not singled out as being especially desirable.

Ayer does teach compressed particles, in the sense that some of the unit operations cited by the Office would result in compressed materials. However, Ayer also fails to teach the criticality of compressed particulates among the broad genus.

In essence, the references cited by the Office, when taken together, fail to provide any motivation to choose compressed particles, or processes that result in compressed particles, over the broad genus of preparatory methods disclosed therein.

Furthermore, **the Office ignores evidence of the superiority of the recited compressed particles and related methods** in release performance, as shown in Figs 2-4, and discussed in the Specification at page 46. The data presented in the Specification suggests that several embodiments of the claimed invention have better release performance as compared to non-inventive examples. This evidence is supportive of the non-obviousness of the present invention, yet it is not addressed at all in the Office's analysis of the non-obviousness of the present invention.

For all of the above reasons, the Office has failed to make out a proper prima facie case of obviousness. Applicants therefore request the withdrawal of the rejection of claims 1, 2, 4-14, 16-28, and 30-35 under 35 U.S.C. § 103(a).

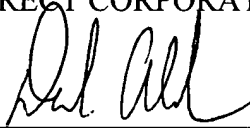
CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (408) 777-4914.

Respectfully submitted,

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Date: 12 Sept. 2008

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